



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m23281

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

January 6, 1999

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

Sybrand Vander Dussen, Owner
Syann Dairy
14950 River Road
Corona, CA 91720

WL 20-9

Dear Mr. Vander Dussen,

An investigation at your dairy operation located at 14900 River Road, Corona, California, conducted by our investigator on December 16 & 18, 1998, confirmed that you offered animals for sale for slaughter as food in violation of Section 402(a)(2)(ii)(C), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

On or about September 18, 1998, you sold a culled dairy cow identified by USDA report #373233 for slaughter as human food at Hallmark Meat Packing. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin at trace levels in the liver and in the kidney at 4.60 p.m. Gentamicin is not approved for use in cattle and no tolerance has been established for residues in the edible tissues of cattle.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack the conditions of an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for the appropriate period of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The following new animal drugs found on your premises, are adulterated under Section 501(a)(5) of the Act, when they are used, as was indicated to our investigator, in a manner contrary to their approved labeling:

Letter to Mr. Vander Dussen

January 6, 1999

Page 2

1. Injectable penicillin G procaine is labeled for a dosage of 1 cc/100 lbs with a maximum of 10 ccs per injection site for up to 4 days. Your use of 20 ccs for up to 8 days is greater than labeled.
2. Injectable ceftiofur sodium (Naxcel) is labeled for administration up to 5 days. Your administration for up to 7 days is greater than labeled.
3. Powdered tetracycline powder is not labeled for intrauterine use in cows. Your use of this drug in an unapproved manner makes the drug unsafe for use.
4. Gentamicin sulfate (Gentocin) is labeled for intrauterine use in horses. Your administration of this drug in a species and for which it is not approved makes this drug unsafe for use.
5. Gentamicin sulfate (Gentadip) is labeled for use as a turkey egg dip. Your intramuscular administration of this drug in a species for which it is not approved makes this drug unsafe for use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action without further notice, such as injunction.

Please note that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made.

Letter to Mr. Vander Dussen

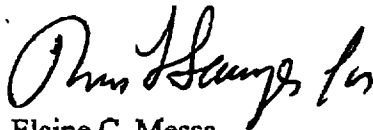
January 6, 1999

Page 3

Your response should be directed to:

Barbara J. Rincon
Consumer Safety Officer
U.S. Food & Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612

Sincerely,



Elaine C. Messa
District Director

cc: Steve Wong, Branch Chief
State of California
Department of Food & Agriculture
P.O. Box 942871
Sacramento, CA 94271-0001